K131336

510(k) Summary for TX Wheelchair Chassis

1. Submission Sponsor

JCM Seating Solutions Ltd
15-18 Maxwell Road
Woodston Industrial Estate
Peterborough
Cambridgeshire PE2 7HU
United Kingdom
Phone: 44 1733 405830
Fax: 44 1733 405838
Contact: Wayne Killick, Operations Director
Website: www.jcmseating.co.uk

OCT 2 8 2013

2. Submission Correspondent

Emergo Group
816 Congress Avenue
Suite 1400
Austin, TX 78701
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Stuart R. Goldman, Senior Consultant, RA/QA
Email: project.management@emergogroup.com

3. Date Prepared

March 19, 2013

4. Device Identification

Trade/Proprietary Name:	TX Wheelchair Chassis
Common/Usual Name:	Wheelchair
Classification Name:	Wheelchair, Mechanical
Classification Regulation:	890.3850
Product Code:	IOR
Device Class:	Class I
Classification Panel:	Physical Medicine

5. Predicate Device

Multi Frame Wheelchair (K100084)

6. Device Description

The TX Wheelchair Chassis is designed and manufactured by JCM Seating Solutions for the mobilization of both our own postural seating systems and those manufactured by other specialist seating providers, and is indicated for occupants

ages 2 to adult, and intended primarily for general indoor and outdoor (smooth surfaces) use.

The chassis consist of a fabricated steel framework with two rear wheels and two front castors where both front and rear wheel sizes can be selected at point of order from a pre-determined range. The TX Wheelchair Chassis also has a "tilt in space" feature that allows for the user's position in space to be changed between -30°/+5°, which may lead to improvements in postural stability and comfort, contributing to enhanced functional activity. A push handle is provided to enable an attendant to propel the chassis and the seated occupant and under certain circumstances the product could be setup to enable the occupant to self-propel through the rear wheels themselves. The chassis and seating system combination can also be used for transporting the occupant in a suitable motor vehicle and has tie-down points to facilitate this.

7. Indication for Use

The TX Wheelchair Chassis is designed and manufactured by JCM Seating Solutions for the mobilization of occupants ages 2 to adult, and intended primarily for general indoor and outdoor (smooth surfaces) use. The chassis and seating system combination can also be used for transporting the occupant in a suitable motor vehicle.

8. Substantial Equivalence Discussion

The following table compares the TX Wheelchair Chassis to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-A – Comparison of Characteristics
Multi Frame Wheelchair vs. TX Wheelchair Chassis

Device Manufacturer	Snug Seat	JCM Seating Solutions	Substantial Equivalence Comparison
Device Trade Name	Multi Frame Wheelchair	TX Wheelchair Chassis	-
FDA 510(k)	K100084	Pending	-
FDA Product Code	IOR	IOR	IOR
FDA Regulation	§ 890.3850	§ 890.3850	§ 890.3850
Frame Construction	Tubular aluminum	Tubular steel	While the subject chassis is made from tubular steel and the predicate chassis is made from tubular aluminum, these differences are

			insignificant as both the subject and predicate device passed performance testing in accordance with FDA recognized consensus standards for mechanical wheelchairs to prove their safety and effectiveness.
Frame Models/Sizes (overall width)	Size 1/Size 2/Size 3 (590/640/690 mm)	TX 30/TX 35 (550/620 mm)	Both the subject and predicate chassis are offered in several different models/frame sizes based on their overall width. The slight difference in size does not affect the intended use of these devices.
Front Wheel Options (diameter)	180 mm	150/200 mm	The subject chassis is offered with front wheels (castors) in two different sizes, while the predicate chassis is offered with front wheels in only one size. The slight difference in sizes does not affect the intended use of these devices.
Rear Wheel Options (diameter)	320/560 mm	300/400/600 mm	The subject chassis is offered with rear wheels in three different sizes, while the predicate chassis is offered with rear wheels in two different sizes. The slight difference in sizes does not affect the intended use of these devices.

Chassis Weight	Size 1/Size 2/Size 3 (320 mm) = 13 kg Size 1/Size 2/Size 3 (560 mm) = 14 kg	TX 30 (300/400/600 mm) = 16-17 kg TX 35 (300/400/600 mm) = 17-18 kg	While the subject chassis is made from tubular steel and the predicate chassis is made from tubular aluminum, these differences are considered to be insignificant in their overall operation by either the user or the user's assistant, as both the subject and predicate devices passed performance testing in accordance with FDA recognized consensus standards for mechanical wheelchairs to prove their safety and effectiveness.
Max. Chassis Load (user/seat/accessories)	100 kg (220 lbs)	110 kg (243 lbs)	While the subject chassis is made from tubular steel and can handle a slightly larger maximum load capacity when compared to the predicate chassis that is made from tubular aluminum, these differences are insignificant as both the subject and predicate devices passed performance testing in accordance with FDA recognized consensus standards for mechanical wheelchairs to

			prove their safety and effectiveness.
Tilt/Prone Seat Angle	0-30°/35°/40°	-30°/+5°	Both the subject and predicate chassis are offered with the ability of their postural seating system (an accessory offered with the chassis by their manufacturer) to be tilted back. In the case of the subject device, the amount of rearward tilt is set at -30°, while in the case of the predicate device the amount of rearward tilt can be positioned to -30°/35°/40° depending on how the seating system is mounted to the frame. While the predicate device also has the ability to tilt forward +5°. The slight difference in forward and rear tilt options between the subject and predicate devices does not affect their overall intended use.
Age of Occupant	Children	2-adult	The subject chassis is designed for occupants ages 2 – adult (18) up to 243 lbs in weight, while the predicate chassis is designed for children up to 220 lbs in weight.
User Environment	General indoor and outdoor use	General indoor and outdoor use	Both the subject and predicate chassis are designed

			for general indoor and outdoor use under normal environmental conditions.
Parking Brakes	Yes	Yes	Both the subject and predicate chassis are offered with a hand operated barking system that engages the rear wheels and can be adjusted to accommodate the different size rear wheel options that each model of device is offered in.
Hand (Drum) Brakes	Yes	Yes	Both the subject and predicate chassis are offered with drum brakes that can be operated by the occupant's assistant, and these brake levers are mounted (one on each side) of the device's push brace that is attached to the chassis frame.
Anti-Tip Mechanism	Yes	Yes	Both the subject and predicate chassis are offered with an anti-tip mechanism by way of a frame mounted anti-tip bar that is attached to the rear of the chassis that can be rotated to either engage or disengage into position.
Seat Plate	Yes	Yes	Both the subject and predicate chassis are offered with an interface

			(seat) plate to which the postural seating system is attached.
Foot Support	Yes	Yes	Both the subject and predicate chassis are offered with a frame mounted foot support (rest) for the occupant to rest their feet on when using the device.
Transport Tie-Down Fittings	Yes	Yes	Both the subject and predicate chassis are offered with a WTORS (Wheelchair Tie Down and Restraint Systems) fittings that allow the chassis/seating system/occupant to be safely secured (tied down) during transport.
Indications for Use	The Multi Frame's intended function and use is to provide mobility to children limited to a sitting position. The Wheelchair consists primarily of an aluminum frame, large rear wheels with hand rims for propelling the wheelchair or smaller rear wheels for attendant-only use, and smaller front pivoting casters for steering and turning.	The TX Wheelchair Chassis is designed and manufactured by JCM Seating Solutions for the mobilization of occupants ages 2 to adult, and intended primarily for general indoor and outdoor (smooth surfaces) use. The chassis and seating system combination can also be used for transporting the occupant in a suitable motor vehicle.	Some minor differences between the subject and predicate device are: ▪The frame of the subject chassis is made of steel, while the frame of the predicate chassis is made from aluminum. ▪Both the subject and predicate chassis are offered in several frame sizes. ▪Both the subject and predicate chassis are offered with different options for their rear wheel diameter, while the

			subject chassis is offered with front wheels in two size diameters, and the predicate device is offered in only one size. •Both the subject and predicate chassis allow for the occupant to be tilted back to a prone position.

9. **Non-Clinical Performance Data**

As part of demonstrating the safety and effectiveness of its TX Wheelchair Chassis and in showing substantial equivalence to the predicate device, JCM Seating Solutions submitted its device for extensive performance testing in accordance with the following FDA guidance document and recognized consensus standards shown below.

- ***Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles***
- **ANSI/RESNA WC-1:2009, *American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters)***

- WC Section 1 – Static Stability
  (Results: Passed)
- WC Section 3 – Determination of the Effectiveness of Brakes
  (Results: Passed)
- WC Section 5 – Overall Dimensions, Mass, and Turning Space
  (Results: Passed)
- WC Section 7 – Measurement of Seating and Wheel Dimensions
  (Results: Passed)
- WC Section 8 – Static, Impact, and Fatigue Strength Dimensions
  (Results: Passed)
- WC Section 15 – Requirements for Information, Disclosure, Documentation, and Labeling
  (Results: Passed)

- **ISO 7176-8:1998, *Wheelchairs -- Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths***
  (Results: Passed)
- **ISO 14971: 2007, *Medical Devices -- Application of Risk Management to Medical Devices***

The TX Wheelchair Chassis passed all the testing in accordance with national and international standards stated above as shown by the acceptable results obtained.

10. Clinical Testing

There was no clinical testing required to support the TX Wheelchair as the indications for use is equivalent to the predicate device. Mechanical wheelchairs, including the predicate device, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise any questions regarding its safety and effectiveness when compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the TX Wheelchair Chassis and the Multi Frame Wheelchair do not raise any questions regarding its safety and effectiveness when used as indicated. Furthermore, the TX Wheelchair Chassis has undergone extensive performance testing in accordance with the applicable sections of ANSI/RESNA WC-1 and ISO 7176-8 to demonstrate its safety. The TX Wheelchair Chassis, as designed and manufactured by JCM Seating

Solutions, is therefore determined to be substantially equivalent to the predicate device manufactured by Snug Seat, Inc., previously cleared under K100084.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 28, 2013

JCM Seating Solutions, Ltd
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K131336
Trade/Device Name: TX Wheelchair Chassis
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: September 30, 2013
Received: October 1, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131336

Device Name: TX Wheelchair Chassis

Indications For Use:

The TX Wheelchair Chassis is designed and manufactured by JCM Seating Solutions for the mobilization of occupants ages 2 to adult, and intended primarily for general indoor and outdoor (smooth surfaces) use. The chassis and seating system combination can also be used for transporting the occupant in a suitable motor vehicle.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S